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Case Number 255,2024

IN THE SUPREME COURT OF THE STATE OF DELAWARE

IN RE ZANTAC (RANITIDINE) LITIGATION	§	No. 255, 2024
	§	
	§	Court Below–Superior Court
	§	of the State of Delaware
	§	
	§	C.A. No. N22C-09-101

Submitted: July 2, 2024
Decided: August 27, 2024

Before **SEITZ**, Chief Justice; **LEGROW** and **GRIFFITHS**, Justices.

ORDER

After consideration of the notice of appeal from an interlocutory order, the supplemental notice of appeal, their exhibits, the appellants' motion to supplement the record, and the legal authority submitted under Supreme Court Rule 15(a)(iv), it appears to the Court that:

(1) Nearly 75,000 plaintiffs (the "Plaintiffs") filed suit in the Superior Court alleging that their ingestion of ranitidine—which is marketed under the brand name Zantac and in which N-Nitrosodimethylamine ("NDMA"), a known carcinogen, is found—caused their cancer diagnoses (the "Zantac Litigation"). The Plaintiffs claim that the manufacturers of prescription and over-the-counter ranitidine products (the "Defendants") collectively bear responsibility for their cancer diagnoses and their related injuries or deaths. The Plaintiffs' claims relate to

ten specific types of cancers: bladder, esophageal, gastric, liver, pancreatic, breast, colorectal, kidney, lung, and prostate.

(2) Under a Superior Court case management order, the Zantac Litigation is proceeding simultaneously on two tracks: (i) the first designed to address "general causation"—that is, whether the ingestion of ranitidine is capable of causing cancer as alleged—and (ii) the second designed to identify representative cases for bellwether discovery and trials. To carry their burden as contemplated by the first track, the Plaintiffs retained ten experts to offer opinions on general causation for each of the named cancers. The Defendants moved to exclude the opinions under Delaware Uniform Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[1]

(3) On May 31, 2024, the Superior Court denied the Defendants' motions to exclude the experts' testimony (the "Order").[2] In addition to addressing the Defendants' challenges to each of the Plaintiffs' ten experts, the court reached certain legal conclusions applicable to all the experts, including that the experts' general causation opinions could be based on studies relating to the ingestion of NDMA, rather than ranitidine itself, and that Delaware law does not "recognize a

[1] 509 U.S. 579 (1993).
[2] *In re Zantac (Ranitidine) Litig.*, 2024 WL 2812168 (Del. Super. Ct. May 31, 2024). The Order also denied the Plaintiffs' motion to exclude a portion of the Defendants' general causation expert's testimony.

'threshold dose' requirement as part of the general causation analysis."[3] The Defendants asked the Superior Court to certify an interlocutory appeal from the Order under Supreme Court Rule 42. The Defendants claimed that the Order made three rulings in connection with its determination that the Plaintiffs' experts' testimony is admissible, each of which decided a substantial issue of material importance—a threshold consideration under Rule 42. The Defendants also argued that three of the Rule 42(b)(iii) factors weighed in favor of certification: (i) the Order conflicts with other trial court decisions (Factor B); (ii) interlocutory review of the Order may terminate the litigation (Factor G); and (iii) interlocutory review of the Order would serve considerations of justice (Factor H). The Plaintiffs opposed the application.

(4) On July 1, 2024, the Superior Court denied the application for certification.[4] The Superior Court found that the Order did not decide a substantial issue of material importance meriting appellate review before a final judgment because the court applied settled law to reach a "routine evidentiary determination."[5] The Superior Court nevertheless considered the Rule 42(b)(iii) factors cited by the Defendants and found that they did not weigh in favor of certification. First, the court concluded that the Order did not, as claimed by the Defendants, conflict with

[3] *Id.* at *7.
[4] *In re Zantac (Ranitidine) Litig.*, 2024 WL 3271976 (Del. Super. Ct. July 1, 2024).
[5] *Id.* at *3.

other trial court decisions. Second, the court disagreed with the Defendants' assertion that interlocutory review was likely to terminate the litigation. Third, the Superior Court found that the Defendants' argument that "it would be unfair to force them to go to trial because of the implications it has on Delaware's corporate image" was not an appropriate basis for relief.[6] Finally, the court concluded that the certain costs of interlocutory review outweighed any possible benefits.

(5) Applications for interlocutory review are addressed to the sound discretion of the Court.[7] When determining whether to accept an interlocutory appeal, the Court may consider all relevant factors, including the trial court's decision whether to certify the interlocutory appeal.[8] In the exercise of our discretion and under the unique circumstances presented by this mass tort litigation, we have concluded that the application for interlocutory review meets the strict standards for certification under Rule 42(b) and should be accepted. A ruling on the issues regarding the Plaintiffs' general causation experts could be dispositive for some or all of the almost 75,0000 claims filed in Delaware; the Defendants agree that discovery and litigation regarding the second track of the case management order may continue while the interlocutory appeal is pending; and, importantly, the Superior Court's decision raises substantial issues regarding the *Daubert* standard

[6] *Id.*
[7] Del. Supr. Ct. R. 42(d)(v).
[8] *Id.*

generally and mass tort litigation specifically, including whether (i) experts may base their causation opinions on studies regarding the cancer-causing agent or must focus on the product at issue in the litigation, and (ii) Delaware law requires experts to identify a threshold dose for purposes of establishing general causation.[9]

NOW, THEREFORE, IT IS ORDERED that the interlocutory appeal is ACCEPTED. The appellants' motion to supplement the record is moot.

BY THE COURT:

/s/ N. Christopher Griffiths
Justice

[9] *See Tumlinson v. Advanced Micro Devices, Inc.*, 2013 WL 7084888, at *7-8 (Del. Super. Ct. Oct. 15, 2013) (excluding a general-causation expert's opinion in part because the expert "refuse[d] to specify dosages" but acknowledging that there have been cases where "imprecision [had] been excused" and "general causation [was] assumed where neither the specific dose required for human toxicity nor the specific dose plaintiffs received [was] known … [where] the substance in question [was] known to be harmful at some exposure level and the plaintiff suffered the precise harm connected to that exposure").